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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/388,221	09/01/1999	JOHN REED C	P-LJ-3650	3565

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	**PAPER NUMBER**
1632	32

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/388,221	Applicant(s) Reed
	Examiner Anne Marie Wehbé	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 11, 2003* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 4-9, 11, 18, 27, 38, and 66-104* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *1, 4, 6-9, 11, 18, 27, 66-69, 71-74, 76-82, 86, 89-97, and 99-104* is/are allowed.

6) ☒ Claim(s) *5, 38, 70, 75, 83-85, 87, 88, and 98* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply*

Continued Prosecution Application

Applicant's amendment received on 3/11/03 has been entered. New claims 89-104 have been entered. Claims 1, 4-9, 11, 18, 27, 38, and 66-104 are pending and active in the instant application. An action on the CPA follows.

Those sections of Title 35, US code, not included in this action, can be found in the previous office action.

Claim Rejections - 35 USC § 112

The rejection of claims 1, 5-7, 18, 38, 66-69, 71-74, and 83-86 under 35 U.S.C. 112, first paragraph, for lack of written description is withdrawn in view of applicant's amendments to the claims.

The rejection of claims 1, 5-7, 18, 38, 66-69, 71-74, and 83-86 under 35 U.S.C. 112, first paragraph, for scope of enablement is maintained over claims 38, 83-85, and new claim 98, and withdrawn over claims 1, 5-7, 18, 66-69, 71-74, and 86. Applicant's arguments as they pertain to the remaining grounds of rejection have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

In regards to methods of modulating apoptosis in cell in vitro by transfecting said cells with a nucleic acid encoding a NAC or functional fragment thereof, the applicant again argues that post-filing evidence previously provided as a publication by Chu et al. (2001) demonstrates that both full length NAC and a fragment of NAC encoding the NAC CARD domain can modulate apoptosis in cell in tissue culture. It is noted that the applicant states for the record that the NAC disclosed by Chu et al. is the same as that disclosed as SEQ ID NO:2 by applicants. Chu et al. teaches that overexpression of a full length NAC, which applicants state is SEQ ID NO:2, is associated with Apaf-1 mediated apoptosis only in the presence of overexpressed Apaf-1 AND pro-Casp9 or overexpressed Apaf-1 and an Apaf-1 apoptosis inducer. Likewise, Chu et al. teaches that the NAC CARD domain inhibits Apaf-1 apoptosis only in the presence of overexpressed Apaf-1 AND pro-Casp9 or overexpressed Apaf-1 and an Apaf-1 apoptosis inducer. The overexpression of the full length NAC or the NAC CARD domain alone did NOT modulate apoptosis. The instant specification neither discloses nor claims the modulation of apoptosis by the expression of NAC or NAC CARD AND Apaf-1 AND pro-Casp9 or an Apaf-1 apoptosis inducer. Thus, a nexus cannot be drawn between the teachings of Chu et al. and the instant invention as claimed. Please note as well, that the claims as written are broad and recite the modulation of apoptosis in any type of cell. The amendment to the claims which indicates that the Apa-f-1 mediated apoptosis is modulated does not place any limitation on the cells to be transfected in the instant method. While the applicant states that the skilled artisan would choose to use cells which overexpress apoptosis modulators such as Apaf-1 and caspace-9, these

limitations are not present in the claims, and since, in patentability context, claims are to be given their broadest reasonable interpretations, limitations are not to be read into claims from the specification. *In re Van Guens*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Please note as well that a feature which is taught as critical to the invention and is not recited in the claims should result in a rejection of such claim under the enablement provision section of 35 U.S.C. 112. See *In re Mayhew* , 527 F.2d 1229,1233, 188 USPQ 356, 358 (CCPA 1976).

The rejection of claims 8-9, 11, 27, 77-81, and 87-88 under 35 U.S.C. 112, second paragraph, for indefiniteness is maintained over claims 87-88 and withdrawn over claims 8-9, 11, 27, and 77-81 in view of applicant's amendments to the claims. The applicant has not amended claims 87-88 or addressed any arguments to claim 87-88. Claims 87-88 depend on claims 77-81 and 82 respectively, and recite the limitation that the oligonucleotides of those claim comprise or consists of 30 contiguous nucleic acids. Claims 77 has been amended to recite wherein the nucleic acid consists of at least 500 contiguous nucleic acids and claim 82 has been amended to recite wherein the nucleic acid consists of at least 100 contiguous nucleic acids. Further, claims 78-81 no longer provide any antecedent basis for "fragments", and instead recite specific nucleotide sequences that are greater than 30 nucleic acids. Thus, the limitations of claims 87-88 are in conflict with the limitations of claims 77-81 and 82.

Claim Rejections - 35 USC § 102

The rejection of claim 8 under 35 U.S.C. 102(b) as being anticipated by GSS sequence submission B33808 is withdrawn in view of applicant's amendment to the claim.

The rejection of claim 82 under 35 U.S.C. 102(b) as being anticipated by EST sequence submission H51863 is withdrawn in view of applicant's amendment to the claim.

Claims 5, 70, and 75 are newly rejected under 35 U.S.C. 102(a) over Nagase et al. (1999) DNA Res., Vol. 6, 63-70. Nagase teaches a novel cDNA clone from human brain cDNA libraries which appears to share >80% sequence identity to SEQ ID Nos: 1 (see pages 65-66, Tables 1+ 2) and which is part of the HUGE human sequence database.Thus, Nagase et al. anticipates the instant invention as claimed.

Nagase et al. has been applied to claims 5, 70, and 75 based on applicant's statement for the record that the NAC sequence disclosed in Chu et al. is the same as the applicant's NAC, see paper no. 30. Chu et al. teaches that the sequence used in their experiments were derived from the KIAA0926 cDNA disclosed by the Kazusa DNA research institute . KIAA0926 is the cDNA clone disclosed on page 65, first column, of Nagase et al. Thus, the sequence disclosed by Nagase et al. as KIAA0926 appears to be identical or at least greater than 80% homologous to SEQ ID NO:1, and encodes a predicted amino acid sequence 100% identical to SEQ ID NO:2.

Claim Rejections - 35 USC § 103

The rejection of claim 8 under 35 U.S.C. 103(a) over Nagase et al. (1999) DNA Res. Vol. 6, 63-70 in view of Nagase et al. (1998) DNA Res. Vol. 5, 277-286. is withdrawn in view of applicant's amendment to the claim.

Nucleotide and/or Amino Acid sequences

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures which is attached to this communication. In particular, please note sequences disclosed in Figure 1D of the specification are not identified by SEQ ID NOS. Applicant is requested to return a copy of the attached Notice To Comply with the response.

Claims 1, 4, 6-9, 11, 18, 27, 66-69, 71-74, 76-82, 86, 89-97, and 99-104 are considered free of the prior art of record and allowable at this time.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Fri from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

Application No.: 09/388,221

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: the sequences in Figure 1D are not indentified by SEQ ID NOS.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:
For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

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